

Appl. No. : 10/035,978  
Filed : December 21, 2001

### AMENDMENTS TO THE CLAIMS

1. (Currently amended) A method for the detection of *Helicobacter pylori* (*H. pylori*) present in a sample comprising the steps of:

amplifying the polynucleic acids of the m and s regions of the vacA gene with a pair of primers, wherein one of said primers is selected from the group consisting of: SEQ ID NOS: 14-18 and, another of said primers is selected from the group consisting of SEQ ID NOS: 23-26 and 277;

hybridizing the polynucleic acid obtained with at least one probe hybridizing to a conserved region of the vacA gene and at least one probe hybridizing to a variable region of the vacA gene, thus forming hybrids, wherein at least one probe hybridizing to the variable region comprises the polynucleotide of claim 14;

detecting the hybrids formed; and

determining the presence or absence of *H. pylori* in a sample from the hybridization signals obtained.

2. (Withdrawn) A method according to Claim 1 wherein said primer pair for the amplification step comprises VA1F (SEQ ID NO:277) and VA1XR (SEQ ID NO:14).

3. (Cancelled)

4. (Cancelled)

5. (Withdrawn) The method of Claim 1 additionally comprising the step of releasing, isolating, or concentrating the *H. pylori* polynucleic acids in the original sample.

6. (Withdrawn) The method according to Claim 1, wherein the hybridization step is a reverse hybridization step, wherein the probes are immobilized on a solid support.

7. (Withdrawn) The method according to Claim 6, wherein said probes are immobilized as parallel lines on a solid support.

8. (Withdrawn) The method according to Claim 6, wherein said solid support is a membrane strip.

9. (Currently amended) A kit for detecting and/or typing *H. pylori* strains in a sample liable to contain it, comprising the following components:

at least one probe selected from the group consisting of: SEQ ID NOS:1-11 and 27-39 or variants thereof, with said probe and/or other probes applied comprising a polynucleotide according to claim 14;

a buffer or components necessary to produce the buffer enabling an amplification  
or a hybridization reaction between said probes and the ~~amplified products~~ sample; and  
a means for detecting the hybrids resulting from said hybridization.

10. (Currently amended) The method according to Claim 97, wherein said solid support is a microtiter plate.

11. (Withdrawn) The method of Claim 1, further comprising amplifying the polynucleic acids of the *cagA* gene of *H. pylori* with a primer pair that amplifies a conserved region of the *cagA* gene of all *H. pylori* strains.

12. (Withdrawn) The method of Claim 5, wherein each primer from said primer pair comprises a primer selected from the group consisting of: SEQ ID NOS: 1, 12-13, 19-22, and 27.

13. (Currently amended) A method according to Claim 1 for the detection and/or typing of alleles of the *cagA* and *vacA* gene of *H. pylori* present in a sample using a set of probes and/or primers specially designed to detect and/or to amplify and/or to type the said alleles, with said probes selected from the group consisting of: SEQ ID NOS: 1-11 and 27-39 and primers being selected from the group consisting of: SEQ ID NOS: 12-26 and variants thereof that can amplify said *vacA* or *cagA* region of all strains of *H. pylori*, wherein one of the probes corresponds to the polynucleotide of claim 14.

Claim 14. (Currently amended) An isolated *vacA* polynucleotide sequence ~~selected from the group consisting of: SEQ ID NOS: 40-91 and SEQ ID NOS: 115-276~~ comprising SEQ ID NO: 126.

15. (Currently amended) A method for the detection and/or typing of *Helicobacter pylori* (*H. pylori*) strains present in a sample comprising the steps of:

amplifying the polynucleic acids of the *m* and *s* regions of the *vacA* gene and a conserved region of the *cagA* gene, with a pair of primers, wherein said *vacA* primers are selected from the group consisting of: SEQ ID NOS: 14-18, 23-26, and 277;

hybridizing the polynucleic acids obtained with at least one probe hybridizing to a conserved region of the *cagA* gene and at least one probe hybridizing to a variable region of the *vacA* gene, thus forming hybrids, wherein at least one probe hybridizing to the variable region comprises the polynucleotide of claim 14;

detecting the hybrids formed;

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detecting and/or typing *H. pylori* strains present in a sample from the differential hybridization signals obtained; wherein said typing comprises the allele-specific detection of a strain according to the vacA polynucleic acid alleles.

16. (Withdrawn) The method of Claim 11, wherein said cagA primers are selected from the group consisting of SEQ ID NOS: 12-13, and 19-22.

17. (Currently amended) The method of Claim 1, wherein said probes ~~has~~have compatible hybridization and wash conditions.

18. (Withdrawn) The method of Claim 11 wherein the hybridization step is a reverse hybridization step, wherein said probes are immobilized on a solid support.

19. (Withdrawn) The method according to Claim 11 wherein the polynucleic acids obtained in the amplification step are immobilized on a solid support and the subsequent hybridization step is carried out on said solid support.

20. (Cancelled)

21. (Cancelled)

22. (Cancelled)

23. (Cancelled)

24. (Currently amended) A method according to claim 11 ~~wherein at least one of said probes is selected from the group consisting of SEQ ID NOS:2-11 and 28-39 and~~ wherein said primers are selected from the group consisting of SEQ ID NOS:14-18 and 23-26.